



Practitioner's Docket No. MWH-0303US2

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Drysdale et al.

Application No.: 09/811,285
Filed: March 16, 2001

Group No.: not assigned
Examiner: not assigned

For: Association of β_2 -Adrenergic Receptor Haplotypes of Drug Response

Assistant Commissioner for Patents
Washington, D.C. 20231

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WITHIN THREE MONTHS OF FILING OR
BEFORE MAILING OF FIRST OFFICE ACTION (37 C.F.R. section 1.97(b))

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INFORMATION DISCLOSURE STATEMENT

The information disclosure statement submitted herewith is being filed within three months of the filing date of the application or date of entry into the national stage of an international application or before the mailing date of a first Office action on the merits, whichever event occurs last. 37 C.F.R. section 1.97(b).

Date: June 18, 2001

Melodie W. Henderson

Melodie W. Henderson
Registration No. 37,848
Telephone Number (203) 786-3421
Customer No. 25106

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 3

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| | |
|------------------------|--------------------|
| Application Number | 09/811,285 |
| Filing Date | 03/16/2001 |
| First Named Inventor | Stephen B. Liggett |
| Group Art Unit | |
| Examiner Name | |
| Attorney Docket Number | MWH-0303US2 |

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U.S. PATENT DOCUMENTS

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FOREIGN PATENT DOCUMENTS

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¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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| | |
|------------------------|--------------------|
| Application Number | 09/811285 |
| Filing Date | 03/16/2001 |
| First Named Inventor | Stephen B. Liggett |
| Group Art Unit | |
| Examiner Name | |
| Attorney Docket Number | MWH-0303US2 |

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

| Examiner's Initials | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
|---------------------|-----------------------|---|----------------|
| BA | | BUSJAHN, ANDREAS ET AL., "B-2 Adrenergic Receptor Gene Variations, Blood Pressure, and Heart Size in Normal Twins," Hypertension, Vol.35, p.555-560, 2000. | |
| BB | | D'AMATO, MAURO ET AL., "Association of Persistent Bronchial Hyperresponsiveness with B2-Adrenergic (ADRB2) Haplotypes," Am. J. Respir. Crit. Care. Med, Vol. 158, p. 1968-1973, 1998. | |
| BC | | DEWAR, J.C. ET AL., "B2-Adrenoceptor Polymorphisms are in Linkage Disequilibrium, but are not Associated with Asthma in an Adult Population," Clinical and Experimental Allergy, Vol. 28, p.442-448, 1998. | |
| BD | | HANCOX, R.J. ET AL., "Polymorphism of the B2-Adrenoceptor and the Response to long-term B2-Agonist Therapy in Asthma," Eur. Respir. J., Vol. 11, p. 589-593, 1998. | |
| BE | | LARGE, VALERIE ET AL., "Human Beta-2 Adrenoceptor Gene Polymorphisms Are Highly Frequent in Obesity and Associate with Altered Adipocyte Beta-2 Adrenoceptor Function," J. Clin. Invest., Vol. 100 (No.12), p.3005-3013, 1997. | |
| BF | | LIPWORTH, B.J. ET AL., "B2-Adrenoceptor Polymorphism and Bronchoprotective Sensitivity with Regular Short- and Long-Acting B2-agonist Therapy," Clinical Science, Vol. 96, p. 253-259, 1999. | |
| BG | | MARTINEZ, FERNANDO D. ET AL., "Association Between Genetic Polymorphisms of the B2-Adrenoceptor and Response to Albuterol in Children With and Without a History of Wheezing," J. Clin. Invest., Vol. 100 (No.12), p. 3184-3188, 1997. | |
| BH | | MCGRAW, DENNIS W. ET AL., "Polymorphisms of the 5' Leader Cistron of the Human B2-Adrenergic Receptor Regulate Receptor Expression," J. Clin. Invest., Vol. 102 (No.11), p. 1927-1932, 1998. | |
| BI | | REIHSAS, ELLEN ET AL., "Mutations in the Gene Encoding for the B2-Adrenergic Receptor in Normal and Asthmatic Subjects," Am. J. Respir. Cell. Mol. Biol., Vol. 8, p. 334-339, 1993. | |
| BJ | | SCOTT, MARK G.H. ET AL., "Identification of Novel Polymorphisms within the Promoter Region of the Human B2-Adrenergic Receptor Gene," British Journal of Pharmacology, Vol. 126, p. 841-844, 1999. | |
| BK | | TIMMERMAN, BERND ET AL., "B-2 Adrenoceptor Genetic Variation is Associated with Genetic Predisposition to Essential Hypertension: The Bergen Blood Pressure Study," Kidney International, Vol. 53, p. 1455-1460, 1998. | |

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| Examiner's Initials | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
|---------------------|-----------------------|---|----------------|
| BL | | WEIR, TRACEY ET AL., "B2-Adrenergic Receptor Haplotypes in Mild, Moderate, and Fatal/Near Fatal Asthma," Am. J. Respir. Crit. Care. Med., Vol. 158, p.787-791, 1998. | |
| BM | | XU, B.Y. ET AL., "B2-Adrenergic Receptor Gene Polymorphisms in Myasthenia Gravis (MG)," Clinical and Experimental Immunology, Vol.119, p.156-160, 2000. | |
| BN | | YAMADA, KENTARO ET AL., "Polymorphism in the 5'-Leader Cistron of the B2-Adrenergic Receptor Gene Associated with Obesity and Type 2 Diabetes," Journal of Clinical Endocrinology & Metabolism, Vol. 84 (No.5), p.1754-1757, 1999. | |
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**CONCISE STATEMENT EXPLAINING RELEVANCE
OF FOREIGN PATENT (WO99/37761)**

The foreign patent application (WO99/37761) by Hoehe et al., is being submitted as a reference in the accompanying Information Disclosure Statement. This reference is believed to be relevant to Applicants' discovery since it discloses several polymorphic sites in the β_2 AR gene (see abstract). This reference also discloses haplotypes of the β_2 AR gene for the polymorphic sites at nucleotide positions 1541, 1568, 1633, and 1666 of the β_2 AR gene (see pages 2, 6, and 7). These positions correspond to PS7, PS8, PS9, and PS10, respectively, in Applicants' U.S. Application (09/811285).